

REMARKS

Applicant has carefully reviewed the Office Action mailed July 15, 2009, prior to preparing this response. Currently claims 1-13 and 19-26 are pending in the application, wherein claims 1-4, 7-13, 19-21 and 24-26 have been rejected and claims 5-6 and 22-23 have been withdrawn consequent an Examiner-induced restriction requirement. Claims 1-3, 5, 10-13, 19 and 26 have been amended, claims 27-29 have been added, and claims 12, 24 and 25 have been cancelled with this paper. Support for the amendments may be found, for example, at lines 3-15 of page 5 and line 19 of page 11 through line 15 of page 14 of the Application as originally filed. No new matter has been added. Favorable consideration of the above amendments and following remarks is respectfully requested.

Claim Rejections under 35 U.S.C. § 102

Claims 1 and 7-13 stand rejected under 35 U.S.C. §102(b) as being anticipated by Roll (U.S. Patent No. 5,419,764). Applicant respectfully traverses this rejection. Claim 12 has been cancelled with this response.

Claim 1, as currently amended, recites that the proximal end of the elongate shaft is connected to the hub assembly such that the elongate shaft extends distally from the distal end of the hub assembly. Applicant respectfully asserts that Roll fails to teach such a device.

In response to Applicant's previous remarks, it was indicated in the Office Action that "Contrary to applicant's assertion of the location of the distal and proximal portions, the proximal and distal portions may be interpreted at varying locations depending on how the medical device is positioned." Applicant respectfully disagrees.

Claims must be "given their broadest reasonable interpretation consistent with the specification." M.P.E.P. §2111, quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). This broadest reasonable interpretation "must also be consistent with the interpretation that those skilled in the art would reach." M.P.E.P. §2111, citing *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999).

As presented in Applicant's previous response, consistent with terminology used in the instant application including the claims, as well as the terminology generally used by those of skill in the art, the term "proximal" means in a direction or region toward the operator and the term "distal" means in a direction or region away from the operator. The usage of the terms "proximal" and "distal" throughout Roll is consistent with this understanding. Applicant submits

that examination requires that the interpretation of the terms "proximal" and "distal" be consistent with the specification and consistent with the interpretation that those of skill in the art would reach, and cannot be arbitrary.

In formulating the rejection, the distal member 104 of the catheter body of Roll is being equated to the claimed hub assembly, and the second tubular portion 113 of the distal member of Roll is being equated to the claimed elongate shaft. In evaluating FIG. 1 of Roll, it is apparent that the second tubular portion 113 extends proximally from the enlarged portion of the distal member 104 into the proximal member 106 of the catheter body 130. Thus, the proximal end of the second tubular portion 113 (equated to the claimed elongate shaft) is not connected to the distal member 104 (equated to the claimed hub assembly) such that the second tubular portion 113 extends distally from the distal end of the distal member 104. This configuration is clearly dissimilar to the configuration currently claimed.

For at least these reasons, Roll does not anticipate independent claim 1. Claims 7-13, which depend from claim 1 and which include additional limitations, are also believed patentable over Roll. Withdrawal of the rejection is respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 1-4, 7-11, 13, 19-21 and 24-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over McGlinch et al. (U.S. Patent No. 7,214,220), in view of Gadberry et al. (U.S. Patent No. 5,217,114). Applicant respectfully traverses this rejection, asserting a *prima facie* case of obviousness has not been established. Claims 24 and 25 have been cancelled with this response.

Claim 1, as currently amended, recites that the interference fit structure includes a first portion having an outer diameter and a second portion having an outer diameter different from the outer diameter of the first portion. The first portion of the interference fit structure is configured to contact and form an interference fit with an inner surface of a generally tubular member having a first inner diameter when the elongate shaft and the interference fit structure are disposed therein, and the second portion of the interference fit structure is configured to contact and form an interference fit with an inner surface of a generally tubular member having a second inner diameter different from the first inner diameter when the elongate shaft and the interference fit structure are disposed therein. The cited combination fails to teach such a structure.

If the O-ring (65) of Gadberry et al. were substituted for the IFM (40) of McGlinch et al. as suggested in the Office Action, which Applicant does not concede, the modification would provide the catheter with an IFM having a single portion (i.e., the outermost radial extent of the O-ring) configured to contact and form an interference fit with the packaging tube taught in McGlinch et al. The modified device would not include two portions of different outer diameters configured to contact and form an interference fit with a plurality of different sizes of tubular members.

Dissimilarly, the interference fit structure of the elongate medical device as claimed in claim 1 is configured to accommodate and form an interference fit with a plurality of different sizes of tubular members, providing versatility in packaging the elongate medical device. Furthermore, the interference fit structure of the elongate medical device as claimed in claim 1 may allow for varying the degree of interference fit with the generally tubular member depending on which portion(s) of the interference fit structure contacts and forms an interference fit with the inner surface of the generally tubular member.

Claim 19, as currently amended, recites a circumferential interference fit member disposed in a channel of the hub assembly. The circumferential interference fit member includes a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring. The gap allows the first portion of the ring to be deflected toward the second portion of the ring when the circumferential interference fit member is disposed in the lumen of the tubular member.

The cited combination of McGlinch et al. and Gadberry et al. fails to teach such a configuration. Namely, the O-ring of Gadberry et al., equated to the claimed interference fit member, is not a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring. Dissimilarly, the O-ring of Gadberry et al. is continuous. The teachings of McGlinch et al. fail to remedy the shortcomings of Gadberry et al.

Claim 26, as currently amended, recites an interference fit member including a second material helically disposed about at least a part of the portion of the hub assembly including the first material.

The cited combination of McGlinch et al. and Gadberry et al. fails to teach such a configuration. Namely, the O-ring of Gadberry et al., equated to the claimed interference fit

member, would not be helically disposed around the hub assembly if McGlinch et al. were modified as suggested in the Office Action.

For at least the reasons stated above, Applicant believes that a *prima facie* case of obviousness has not been established with the cited combination. Withdrawal of the rejection of claims 1-4, 7-11, 13, 19-21 and 24-26 under §103(a) is respectfully requested.

Claim 12 stands rejected under 35 U.S.C. §103(a) as being unpatentable over McGlinch et al. (U.S. Patent No. 7,214,220), and Gadberry et al. (U.S. Patent No. 5,217,114), and further in view of Roll (U.S. Patent No. 5,419,764). Claim 12 has been cancelled with this response, rendering this rejection moot.

New Claims

Claims 27-29 have been added with this paper. Claim 27 depends from claim 26 and claims 28-29 depend from claim 1. For at least the reasons stated above regarding the patentability of claims 1 and 26, these claims are also believed patentable over the cited prior art. Favorable consideration of these claims is respectfully requested.

Conclusion

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,



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